



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

András Kónya *et al.*

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Filed: February 1, 2000

For: WOVEN INTRAVASCULAR DEVICES  
AND METHODS FOR MAKING THE  
SAME AND APPARATUS FOR  
DELIVERY OF THE SAME

Group Art Unit: 3731

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APPEAL BRIEF

**Mail Stop – Appeal Brief**  
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Sir:

Appellants submit this Appeal Brief to the Board of Patent Appeals and Interferences in response to the September 14, 2004 final Office Action. The Notice of Appeal filed by Applicants was stamped received by the Patent Office on September 22, 2004. Applicants petition for a 4-month extension of time in which to file this Appeal Brief, bringing the due date to May 22, 2005. If the check has not been included, the Commissioner is authorized to deduct the small-entity

process fee for this extension of time, as well as any other fees that are due relating to this Appeal Brief, from Fulbright & Jaworski Deposit Account No.: 50-1212/UTKO:002US.

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## **I. REAL PARTY IN INTEREST**

The real party in interest in this appeal is the Assignee of the application, Board of Regents, The University of Texas System, 201 West 7th Street, Austin, Texas 78701. IDev Technologies, Inc., 1110 NASA Parkway, Suite 311 Houston, Texas 77058, is the Assignee's exclusive licensee of the technology claimed in the application.

## **II. RELATED APPEALS AND INTERFERENCES**

At present, there are no related appeals or interferences.

## **III. STATUS OF CLAIMS**

Claims 1-108 are pending. Claims 37-66 have been withdrawn as drawn to a nonelected invention. Claims 17, 28, 34, 87 and 106 are objected to, but would be allowable if rewritten in independent form. Claims 1-16, 18-27, 29-33, 35, 36, 67-86, 88-105, 107 and 108 are under active examination, have been rejected and are the subject of the present appeal. A copy of the claims involved in this appeal is attached at the Claims Appendix.

## **IV. STATUS OF AMENDMENTS**

No amendment has been filed subsequent to the final Office Action.

## **V. SUMMARY OF CLAIMED SUBJECT MATTER**

Independent claim 1 is directed to a device comprising a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure, the body having first and second ends, the shape memory wires crossing each other to form a plurality of cells and a plurality of angles, at least one of the angles being obtuse, at least one of the cells being defined by only four sides, and both ends of at least one shape memory wire being located proximate one end of the body. The value of the at least one obtuse angle may be increased by

axially compressing the body. (*Exemplary support can be found in the specification at page 8, lines 18-24; device 10 in FIGS. 1A and 47A (which show cells defined by only four sides).*)

Independent claim 20 is directed to a device comprising a body suitable for implantation into an anatomical structure, the body having a first end, a second end and being defined by at least n shape memory wires, wherein n is greater than one, the n shape memory wires being arranged such that the body comprises a first portion, the first portion comprising a first woven portion and at least one strut, the shape memory wires of the first woven portion crossing each other to form a plurality of cells and a plurality of angles, at least one of the angles being obtuse, at least one of the cells being defined by only four sides, and both ends of at least one shape memory wire being located proximate one end of the body. The value of the at least one obtuse angle may be increased by axially compressing the body. (*Exemplary support can be found in the specification at page 9, line 22 – page 10, line 2; and page 51, lines 23-27 (defining “struts”); page 85, line 1 – page 86, line 28; and struts 408 in FIGS. 51-53.*)

Independent claim 67 is directed to an occluding system comprising a plurality of shape memory wires woven together to form a body useful for occluding an anatomical structure, the body having first and second ends, both ends of at least one shape memory wire being located proximate one end of the body, the shape memory wires crossing each other to form a plurality of cells and a plurality of angles, at least one of the angles being obtuse, and at least one of the cells being defined by only four sides. The value of the at least one obtuse angle may be increased by axially compressing the body. (*Exemplary support can be found in the specification at page 14, lines 15-21; page 58, line 15 – page 59, line 14; body 700 in FIGS. 33A-35 (which show cells defined by only four sides).*)

Independent claim 68 is directed to a device comprising a body suitable for implantation into an anatomical structure, the body having an axis, a first end and a second end, wherein the body comprises a shape memory wire having a first segment and a second segment, the segments being separated by a bend in the shape memory wire located proximate one end of the body, the first segment extending helically in a first direction around the axis toward the other end of the body, the second segment extending helically in a second direction around the axis toward the other end of the body, the first and second segments crossing each other in a plurality of locations, and the first and second segments alternating being farther from the axis at each location. (*Exemplary support can be found in the specification at page 15, lines 3-10; page 32, lines 10-15; body 10 in FIG. 50B.*)

Independent claim 69 is directed to a device comprising a body suitable for implantation into an anatomical structure, the body having a first end and a second end, wherein the body comprises a shape memory wire having a first segment and a second segment, the segments being separated by a bend in the wire located proximate one end of the body, the first segment and second segments being arranged to form loops and twisted segments such that at least two contiguous substantially closed loops are separated from another loop by a twisted segment. (*Exemplary support can be found in the specification at page 15, lines 18-25; page 32, lines 8-9 and 24-27; body 10 in FIG. 50C.*)

Independent claim 70 is directed to a device comprising a body suitable for implantation into an anatomical structure, the body having two ends and comprising a shape memory wire having a first segment and a second segment, the segments being separated by a bend in the wire located proximate one end of the body, the segments being secured to each other in loop-defining locations, the segments also extending between the loop-defining locations in spaced relation to

each other so as form at least two loops, at least one of the at least two loops having a compressed shape. (*Exemplary support can be found in the specification at page 16, lines 6-14; page 61, line 1 – page 62, line 4; body 700 in FIG. 57B.*)

Independent claim 71 is directed to a device comprising a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure, the body having a first end, a second end, and an intersection of two shape memory wires crossed in non-interlocking fashion. Both ends of at least one shape memory wire are located proximate one end of the body, and the two crossed wires form an obtuse angle that may be increased by axially compressing the body. (*Exemplary support can be found in the specification at page 26, lines 11-12, page 33, line 20 – page 36, line 21 and page 39, line 20 – page 42, line 15 (discussing one manner of making device (plain weaving) that will result in wires crossed in non-interlocking fashion); page 26, lines 13-22; body 10 in FIGS. 1A and 47A; wires 5 in FIG. 2.*)

Independent claim 90 is directed to a device comprising a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure, the body having a first end, a second end, a middle, and an intersection of two shape memory wires crossed in non-interlocking fashion. Both ends of at least one shape memory wire are located nearer one end of the body than the middle, and the two crossed wires form an obtuse angle that may be increased by axially compressing the body. (*Exemplary support can be found in the specification at page 26, lines 11-12, page 33, line 20 – page 36, line 21 and page 39, line 20 – page 42, line 15 (discussing one manner of making device (plain weaving) that will result in wires crossed in non-interlocking fashion); page 26, lines 13-22; body 10 in FIGS. 1A and 47A; wires 5 in FIG. 2.*)

## **VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL**

The issues for the Board's consideration are:

(1) whether claims 1-16, 18-27, 29-33, 35, 36, 67, 68, 71-86, 88-105, 107 and 108 are properly rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 4,655,771 (“Wallsten”) (Ex. 1 of Evidence Appendix, and first entered by the Office in the November 21, 2003 Office Action) in view of U.S. Patent No. 5,800,519 (“Sandock”) (Ex. 2 of Evidence Appendix, and first entered by the Office in the November 21, 2003 Office Action;

(2) whether claim 69 is properly rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,968,088 (“Hansen”) (Ex. 3 of Evidence Appendix and first entered by the Office in the November 20, 2002 Office Action); and

(3) whether claims 69 and 70 are is properly rejected under 35 U.S.C. § 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Hansen.

## **VII. ARGUMENT**

### **A. The Office Fails to Carry Its Burden of Establishing a *Prima Facie* Case of Obviousness of Claims 1-16, 18, and 19**

Claims 1-16, 18 and 19 are patentable over the asserted combination of Wallsten and Sandock. The Office has failed to establish a *prima facie* case of obviousness with respect to these claims because there is no **substantial evidence** of a proper motivation for its asserted combination. The Office picks and chooses features of Sandock that cannot be divorced from the remainder of Sandock’s teachings, and it relies on a motivation that does not exist.

Claims 3, 4 and 19 are patentable for additional, independent reasons.

#### **1. Claim 1**

Claim 1 is directed to a device comprising a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure. The body has first and second ends. The shape memory wires cross each other to form a plurality of cells and a plurality of angles. At least one of the angles is obtuse. At least one of the cells is defined by only

four sides. Both ends of at least one shape memory wire are located proximate one end of the body.

The value of the at least one obtuse angle may be increased by axially compressing the body.

An exemplary, non-limiting embodiment of the subject matter of claim 1 appears in

FIG. 1A:

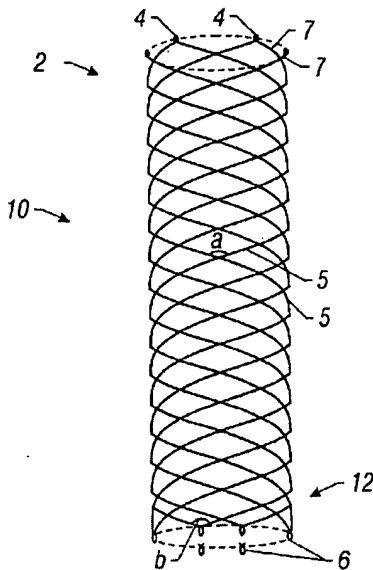


FIG. 1A

a. **Sandock's teachings are not combinable with those of Wallsten**

The Office's argument about what Sandock discloses, and what would be obvious to combine with Wallsten, is not supported by substantial evidence. The Office asserts that:

Sandock teaches that helical wires 11 of a stent should be arranged such that both ends of each wire are located at one end 19 of the body while the wire at the other end 18 of the body is formed into a bend rather than a free end (col. 5, lines 22-55). This arrangement has the apparent advantage of reducing the number of free ends on the wires, which free ends could damage the blood vessel during stent insertion. It would have been obvious to locate both ends of each Wallsten wire at one end of the body and provide a bend in the wire at the opposite end of the body so that it too would have this advantage.

Final Office Action at pp. 1-2. The Office elaborates on its assertion later in the same paper:

As to claim 1, Sandock teaches that helical wires 11 of a stent should be arranged such that both ends of each wire are located at one end 19 of the body while the wire at the other end 18 of the body is formed into a bend rather than a free end. Thus,

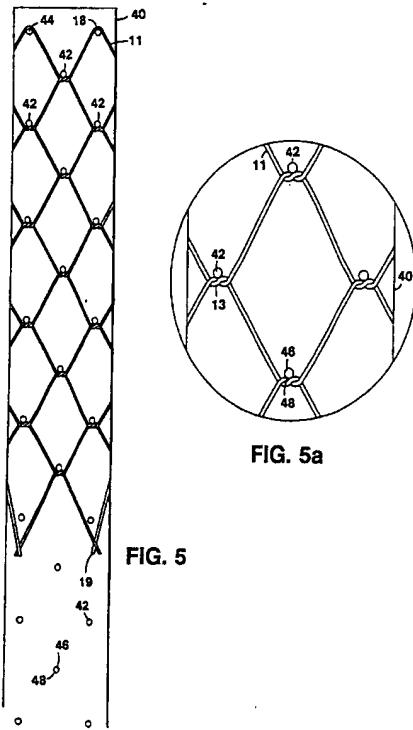
instead of forming a free end of each wire at end 18, Sandock teaches forming a bend at the wire.

Final Office Action at p. 5. There are many problems with these statements about Sandock's teaching, and about the combinability of Sandock's teachings with those of Wallsten.

**(1) The Office Is Improperly Picking and Choosing from Sandock**

The claim limitation at issue is "both ends of at least one shape memory wire being located proximate one end of the body." The Office picks this limitation from Sandock while ignoring its relationship to the remainder of Sandock's stent. The **only reason** Sandock discloses both ends of one wire being located proximate one end of its stent body is because Sandock uses his critical interlocking joints to create his stent. It is clear from Sandock that the interlocking joints cannot be dissociated from the limitation at issue. Moreover, the Office cites to **no evidence** that supports its position that one of ordinary skill in the art would be motivated to divorce the limitation at issue from Sandock's critical interlocking joints.

FIGS. 5 and 5a of Sandock show Sandock's critical interlocking joints:



Multiple strands 11 are bent over pins 44 at the distal end 18 of the prosthesis, and then pulled diagonally downward to an adjacent anchoring pin 42 where they are helically wrapped about each other at least one full time to form interlocking joints 13.<sup>1</sup> This process is repeated until the desired length of the prosthesis is achieved. Sandock (Ex. 2) at col. 5, lines 27-40.

FIGS. 5 and 5a of Sandock show the results of the interlocking joint creation using one full turn. These figures make clear that Sandock's disclosure of the "both ends" limitation is a **direct result of, and is necessarily preceded by**, Sandock's use of the interlocking joints to build his stent.

Those interlocking joints are the focus of Sandock's patent. Sandock extensively discusses them, and the effect they have on the manipulability of the resulting stent, throughout his patent. *See, e.g.*, Sandock (Ex. 2) at col. 1, lines 48-52; col. 2, lines 43-47; col. 3, lines 16-31; col. 4, line 29 – col. 5, line 40; col. 6, lines 7-25; col. 6, line 44 – col. 7, line 15. The interlocking joints are recited in every Sandock patent claim. *Id.* at cols. 8-12.

**Nothing** in Sandock suggests that the result of locating both ends of at least one wire proximate one end of prosthesis 10 could or should be achieved in any fashion **other than** through the creation of all the interlocking joints.

Despite this, the Office divorces the **necessary** creation of Sandock's interlocking joints from the resulting achievement of locating two ends of one wire proximate end 19 of prosthesis 10 **by pointing only** to the bend in the wire at stent end 18 and to the two wire ends at stent end 19:

As to claim 1, Sandock teaches that helical wires 11 of a stent should be arranged such that both ends of each wire are located at one end 19 of the body while the wire at the other end 18 of the body is formed into a bend rather than a free end. Thus, instead of forming a free end of each wire at end 18, Sandock teaches forming a bend at the wire.

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<sup>1</sup> The reference numbers used in this section are from the Sandock patent.

Final Office Action at p. 5. However, the wire bend located at stent end 18 and the free ends of the wire at stent end 19 **do not exist in a vacuum**. Instead, both ends of at least one wire 18 are located proximate end 19 **only because** that wire—along with many others—is **first** bent around a pin 44 **and then** pulled diagonally downward to an adjacent anchoring pin 42 where they are helically wrapped about each other at least one full time to form **the critical** interlocking joints 13 until the desired length of the prosthesis is achieved. Sandock (Ex. 2) at col. 5, lines 27-40.

The Office’s assertion that one of ordinary skill in the art would take away from Sandock **only** the bent wires at end 18 of prosthesis 10 and both ends of at least one wire are located proximate opposite end 19 of prosthesis 10 and not the **intervening and critical** interlocking joints necessary to position those two wire ends proximate end 19 is “nothing more than a hindsight ‘reconstruction’ of the claimed invention by relying on isolated teachings of the prior art without considering the over-all context within which those teachings are presented.” *In re Mercier*, 515 F.2d 1161, 1166, 185 USPQ 774, 778 (CCPA 1975). “It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.” *In re Wesslau*, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965); *cf. McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354, 60 USPQ2d 1001, 1010 (Fed. Cir. 2001) (improper to combine features of secondary reference with primary reference in way that eliminates primary reference features required for successful operation of primary reference invention).

For this reason, the Office has failed to carry its burden of establishing a *prima facie* case of obviousness of claim 1, and the rejection should of this claim and dependent claims 2-16 and 18-19 should be reversed.

## (2) There Is No Motivation for the Asserted Combination

The Office's asserted motivation fails because it has not considered the prior art **as a whole**.

*See Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984) ("[T]he question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination."). A suitable motivation may come from "the nature of the problem," "the teachings of the pertinent references," or "the ordinary knowledge of those skilled in the art." *In re Rouffet*, 149 F.3d 1350, 1355, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998). No such motivation exists.

The Office asserts that the motivation to make the combination is the "apparent advantage" of reducing the number of free ends that comes from "both ends of each wire [being] located at one end 19 of the [Sandock] body while the wire at the other end 1 of the body is formed into a bend rather than a free end (col. 5, lines 22-55)." Final Office Action at p. 1. The Office posits that "[i]t would have been obvious to locate both ends of each Wallsten wire at one end of the body and provide a bend in the wire at the opposite end of the body so that it too would have this advantage." *Id.*<sup>2</sup> However, the Office's asserted motivation is belied when the claimed subject matter is viewed as a whole and the teachings of the references are viewed as a whole. In short, the Office's asserted motivation is not supported by substantial evidence. *In re Lee*, 227 F.3d 1338, 1342, 61 USPQ2d 1430, 1432 (Fed. Cir. 2002).

Claim 1 is directed to a device comprising a plurality of shape memory wires **woven** together to form a body suitable for implantation into an anatomical structure. The body has first and second ends. The shape memory wires cross each other to form a plurality of cells and a

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<sup>2</sup> Note that claim 1 recites only that both ends of at least one wire (not necessarily all wires) be located proximate one end of the body.

plurality of angles. At least one of the angles is obtuse. **At least one of the cells is defined by only four sides.** Both ends of at least one shape memory wire are located proximate one end of the body. The value of the at least one obtuse angle may be increased by axially compressing the body.

Many of Sandock's teachings are inconsistent with those of the claimed subject matter. *See In re Fine*, 837 F.2d 1071, 1074-75, 5 USPQ2d 1596, 1599 (Fed. Cir. 1988) (noting that teachings of one of cited references were "inconsistent with the claimed invention, to some extent"). Sandock's stents **are not woven** because Sandock's joints are interlocking. Furthermore, Sandock's cells all have **at least 5 or more sides** (the cells in the middle all have 6 sides, the cells at the top have 5, and any cells at the bottom that are formed by joining wire ends have 5). Thus, Sandock concerns a very different type of stent than the one claimed, or the one disclosed in Wallsten.

Furthermore, Wallsten identifies the issue of free wire ends cited by the Office, and addresses it. *See* Wallsten (Ex. 1) at col. 3, lines 29-30 ("The free ends of the thread elements of the tubular body can be modified or protected in several ways."). Specifically, Wallsten addresses the issue in 4 different ways in column 3, lines 29-51:

- "make the tubular body as a whole of one coherent element";
- attach U-shaped members pair-wise to the ends of nearby wires;
- weld together crossing points of the wires in a ring around the device, severing the string of woven material just outside the welded locations creating the ring, and folding inwardly any ends that extend beyond the ring; and
- bending the free ends of the elements to form loops.

By providing these options, Wallsten **addresses** the free wire ends issue identified by the Office. As a result, **there is no "problem" to solve**, and no logical reason to look to Sandock, which concerns a completely different way of creating stents. *See In re Nomiya*, 184 USPQ 607,

612-613 (CCPA 1975) (holding that it is improper to conclude that an invention is obvious absent evidence that one of ordinary skill would have recognized that an underlying problem existed).

Wallsten teaches creating stents by severing a long string. Wallsten (Ex. 1) at col. 3, lines 33-35. The Office's suggestion of creating a bend in a wire at one end (as done in Sandock) and weaving the Wallsten stent such that both ends of the wire are located proximate one end of the stent **would impair** the creation of stents in that manner, thus slowing down the stent creation process. This is an additional reason that one of ordinary skill in the art would not alter Wallsten's teachings as suggested by the Office.

Sandock also discloses different ways of addressing the free wire ends at end 19 of prosthesis 10, **none of which** involve starting with bends at the opposite end. Those ways include:

- after heat treatment, joining the ends by ball welding;
- after heat treatment, twisting wire ends helically and then ball welding the ends;
- after heat treatment, elastically bending the wires around the bottom portion of each anchoring pin, slipping them into a sleeve (such as a spring), and welding them to at least one of the spring so that they will not slip free; and
- prior to heat treatment, the strands at end 19 may be joined.

Sandock (Ex. 2) at col. 5, lines 44-60. Sandock's teaching is further evidence that the prior art, taken as a whole, does not suggest the desirability of what the Office has asserted.

In light of these considerations, the Office appears to be relying on what the Examiner believes is "common knowledge" in the art as the primary and sole basis for the asserted obviousness of claim 1. However, it is clear from the teachings of the cited references discussed above and the claimed subject matter as a whole that the Office's proposed motivation – *i.e.*, that one of ordinary skill in the art would believe that the potential damage that free wire ends could cause during insertion should be remedied by providing both ends of at least one wire proximate

one end of the body while locating a bend in that wire at another end of the body<sup>3</sup> – is not “capable of such instant and unquestionable demonstration so as to defy dispute.” *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970). Accordingly, the Office’s position is not supported by substantial evidence.

As the Federal Circuit explained in *Zurko*:

With respect to **core factual findings** in a determination of patentability, however, the Board cannot simply reach conclusions based on its own understanding or experience – or on its assessment what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.

*In re Zurko*, 258 F.3d 1379, 1386, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001) (emphasis added); accord *In re Lee*, 277 F.3d at 1344-45, 61 USPQ2d at 1434-35. The MPEP provides instruction that follows the *Zurko* decision. MPEP § 2144.03 at 2100-138 (“It is never appropriate to rely **solely** on common knowledge in the art without evidentiary support in the record as the principal evidence on which the rejection was based.”) (citing *In re Zurko*, 258 F.3d at 1386, 59 USPQ2d at 1697).

There simply is **no evidentiary support** for the Office’s assertion that the issue of free wire ends would motivate one of ordinary skill in the art to modify the stent creation process in Wallsten by locating two wire ends proximate one end of the Wallsten stent while locating a bend in that wire at another end of the stent. The cited references, viewed as a whole, do not support that notion:

- Sandock and Wallsten create stents in very different ways;
- Sandock requires interlocking joints to create stents – he makes no mention of locating two wires proximate end 19 of stent 10 **in any other manner**;

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<sup>3</sup> Note that claim 1 does not require placement of a bend in a wire at an end of the claimed device.

- Wallsten offers four different solutions to the free wire end issue, none of which suggest the location of two ends of the same wire proximate one end of his stent;
- Sandock offers different solutions to deal with his free wire ends, none of which suggest the location of two ends of the same wire proximate one end of his stent; and
- modifying Wallsten as suggested by the Office would eliminate the ability to create stents by severing a long string, as Wallsten teaches, thus slowing down the Wallsten stent creation process.

For these additional reasons, the Office's asserted motivation for its asserted combination is not supported by substantial evidence, and the rejection of claim 1 and dependent claims 2-16, 18 and 19 should be reversed.

## **2. Claim 3**

Claim 3 is separately patentable for an additional reason. Claim 3 recites that the shape memory wires comprise FePt, FePd or FeNiCoTi. The Office bases the rejection of this claim on the asserted combination of Wallsten and Sandock (Final Office Action at pp. 1-2), but neither reference teaches or suggests any of these materials. On this ground alone, the Office has failed to establish a *prima facie* case of obviousness with respect to claim 3, and the rejection should be reversed. Applicants requested that the Office specifically explain how the asserted combination applies to this claim on pages 16 and 17 of their May 21, 2004 response, but the Office did not do so. Accordingly, the Office has not complied with 37 C.F.R. § 1.104(c)(2).

## **3. Claim 4**

Claim 4 is separately patentable for an additional reason. Claim 4 recites that the shape memory wires comprise FeNiC, FeMnSi or FeMnSiCrNi. The Office bases the rejection of this claim on the asserted combination of Wallsten and Sandock (Final Office Action at pp. 1-2), but neither reference teaches or suggests any of these materials. On this ground alone, the Office has failed to establish a *prima facie* case of obviousness with respect to claim 4, and the rejection

should be reversed. Applicants requested that the Office specifically explain how the asserted combination applies to this claim on pages 16 and 17 of their May 21, 2004 response, but the Office did not do so. Accordingly, the Office has not complied with 37 C.F.R. § 1.104(c)(2).

#### **4. Claim 19**

Claim 19 is separately patentable for an additional reason. Claim 19 depends from claim 18, which recites that the device of claim 1 further comprises a first tube configured to accept a guide wire; and a second tube configured to fit over the first tube. Claim 19 recites that the second tube is placed over the first tube, one end of the body is secured to the first tube and the other end of the body is secured to the second tube.

The Office bases the rejection of this claim on the asserted combination of Wallsten and Sandock (Final Office Action at pp. 1-2), but neither reference teaches or suggests a second tube placed over a first tube, one end of the claimed body being secured to the first tube, and the other end of the body being secured to the second tube. Wallsten discloses two tubes: thin-walled flexible tube 34 and outer flexible tube 35. However, both ends of elastic body 20 are secured to flexible tube 34, using annular member 36 at end 32 and annular member 37 at end 33. *See* Wallsten (Ex. 1) at col. 6, lines 35-66 and FIG. 6. On this ground alone, the Office has failed to establish a *prima facie* case of obviousness with respect to claim 19, and the rejection should be reversed. Applicants requested that the Office specifically explain how the asserted combination applies to this claim on pages 16 and 17 of their May 21, 2004 response, but the Office did not do so. Accordingly, the Office has not complied with 37 C.F.R. § 1.104(c)(2).

#### **B. The Office Fails to Carry Its Burden of Establishing a *Prima Facie* Case of Obviousness of Claims 20-27, 29-33, 35 and 36**

Claims 20-27, 29-33, 35 and 36 are patentable over the asserted combination of Wallsten and Sandock. The Office has failed to establish a *prima facie* case of obviousness with respect to

these claims for the same reasons as those given above in section VII.A.1.a. Furthermore, the Office has misconstrued the term “strut.”

Claims 22, 23, 25-27 and 36 are patentable for additional, independent reasons.

### 1. **Claim 20**

Claim 20 is directed to a device that comprises a body suitable for implantation into an anatomical structure. The body has a first end, a second end and is defined by at least n shape memory wires, wherein n is greater than one. The n shape memory wires are arranged such that the body comprises a first portion. The first portion comprises a first woven portion and at least one strut. The shape memory wires of the first woven portion cross each other to form a plurality of cells and a plurality of angles, at least one of the angles being obtuse. At least one of the cells is defined by only four sides, and both ends of at least one shape memory wire are located proximate one end of the body. The value of the at least one obtuse angle may be increased by axially compressing the body.

The reasoning provided above in section VII.A.1.a. about why the asserted combination of Wallsten and Sandock fails with respect to claims 1-16, 18 and 19 applies with equal force to the asserted obviousness of this claim and its dependent claims. On those grounds, the obviousness rejection of claims 20-27, 29-33, 35 and 36 should be reversed.

The obviousness of claims 20-27, 29-33, 35 and 36 should be reversed for the additional reason that the Office has not established that Wallsten, as the Office asserts, discloses or suggests the claimed “at least one strut.” The Office asserts that the claimed “at least one strut” “comprises, for example, a segment of one of the wires.” Final Office Action at p. 5. This is not supported by substantial evidence.

Applicants defined the term “strut” at lines 23-27 of page 51 of the application:

As used herein, “struts” means segments of wires that are joined together in any suitable manner such as twisting, encasing within a sufficiently flexible piece of tubing, soldering, welding, *etc.*, such that the portion of the stent formed from the struts is less disruptive of the blood flow therethrough than would be the same portion formed from a weave.

This clear definition controls the meaning of “strut.” MPEP 2111.01 at 2100-50 (“Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim.”). Non-limiting examples of a strut are shown by element 408 in FIGS. 51-53:

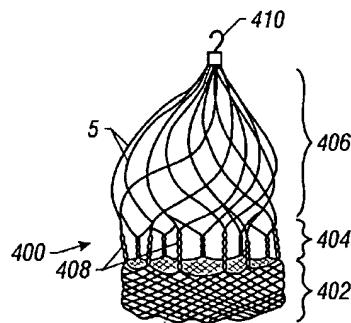


FIG. 51

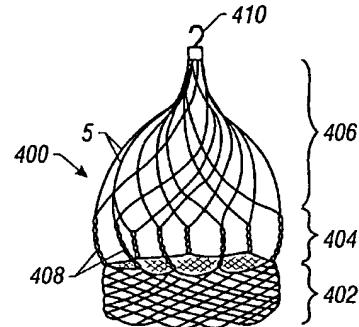


FIG. 52

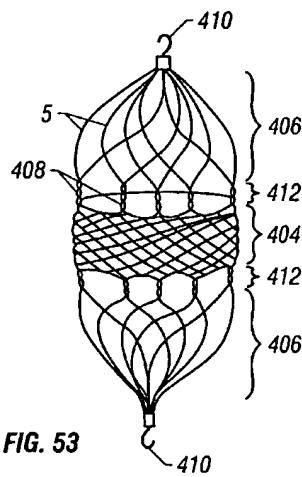


FIG. 53

This definition specifies that a strut includes segments (**plural**) of wires that are joined together in any suitable manner. The Office’s argument that a **single** segment of wire can be a strut

is inconsistent with this definition. Accordingly, the rejection of claims 20-27, 29-33, 35 and 36 should be reversed for this additional reason.

## **2. Claim 22**

Claim 22 is separately patentable for an additional reason. Claim 22 recites that the shape memory wires comprise FePt, FePd or FeNiCoTi. The Office bases the rejection of this claim on the asserted combination of Wallsten and Sandock (Final Office Action at pp. 1-3), but neither reference teaches or suggests any of these materials. On this ground alone, the Office has failed to establish a *prima facie* case of obviousness with respect to claim 22, and the rejection should be reversed. Applicants requested that the Office specifically explain how the asserted combination applies to this claim on pages 16 and 17 of their May 21, 2004 response, but the Office did not do so. Accordingly, the Office has not complied with 37 C.F.R. § 1.104(c)(2).

## **3. Claim 23**

Claim 23 is separately patentable for an additional reason. Claim 23 recites that the shape memory wires comprise FeNiC, FeMnSi or FeMnSiCrNi. The Office bases the rejection of this claim on the asserted combination of Wallsten and Sandock (Final Office Action at pp. 1-3), but neither reference teaches or suggests any of these materials. On this ground alone, the Office has failed to establish a *prima facie* case of obviousness with respect to claim 23, and the rejection should be reversed. Applicants requested that the Office specifically explain how the asserted combination applies to this claim on pages 16 and 17 of their May 21, 2004 response, but the Office did not do so. Accordingly, the Office has not complied with 37 C.F.R. § 1.104(c)(2).

## **4. Claim 25**

Claim 25 is separately patentable for an additional reason. Claim 25 recites that the first portion comprises a first woven portion separated from a second woven portion by multiple first

struts. An example of such a body is shown, for example, in FIG. 51 above (note woven portions 406 and 402). As explained, a segment of a wire is not a strut, as asserted by the Office. Wallsten does not disclose or suggest multiple struts that separate a first woven portion from a second woven portion. On this ground alone, the Office has failed to establish a *prima facie* case of obviousness with respect to claim 25, and the rejection should be reversed. Applicants requested that the Office specifically explain how the asserted combination applies to this claim on pages 16 and 17 of their May 21, 2004 response, but the Office did not do so. Accordingly, the Office has not complied with 37 C.F.R. § 1.104(c)(2).

#### **5. Claim 26**

Claim 26 is separately patentable for an additional reason. Claim 26 recites that the first portion of claim 25 has a generally domed shape. *See, e.g.*, dome-shaped portion 406 in FIG. 51 above. The Office does not explain which reference teaches or suggests a dome shaped woven portion. Neither reference does. On this ground alone, the Office has failed to establish a *prima facie* case of obviousness with respect to claim 26, and the rejection should be reversed. Applicants requested that the Office specifically explain how the asserted combination applies to this claim on pages 16 and 17 of their May 21, 2004 response, but the Office did not do so. Accordingly, the Office has not complied with 37 C.F.R. § 1.104(c)(2).

#### **6. Claim 27**

Claim 27 is separately patentable for an additional reason. Claim 27 recites that the first portion of claim 25 has a generally domed shape and the multiple first struts are bent slightly to increase the self-anchoring capability of the body in an anatomical structure. *See, e.g.*, the shape of struts 408 in FIG. 52 above. The Office does not explain which reference teaches or suggests a dome shaped woven portion or multiple struts that are bent slightly to increase the self-anchoring

capability of the body in an anatomical structure. Neither reference does. On this ground alone, the Office has failed to establish a *prima facie* case of obviousness with respect to claim 27, and the rejection should be reversed. Applicants requested that the Office specifically explain how the asserted combination applies to this claim on pages 16 and 17 of their May 21, 2004 response, but the Office did not do so. Accordingly, the Office has not complied with 37 C.F.R. § 1.104(c)(2).

## 7. **Claim 36**

Claim 36 is separately patentable for an additional reason. Claim 36 depends from claim 35, which recites that the device of claim 20 further comprises a first tube configured to accept a guide wire; and a second tube configured to fit over the first tube. Claim 36 recites that the second tube is placed over the first tube, one end of the body is secured to the first tube and the other end of the body is secured to the second tube.

The Office bases the rejection of this claim on the asserted combination of Wallsten and Sandock (Final Office Action at pp. 1-3), but neither reference teaches or suggests a second tube placed over a first tube, one end of the claimed body being secured to the first tube, and the other end of the body being secured to the second tube. Wallsten discloses two tubes: thin-walled flexible tube 34 and outer flexible tube 35. However, both ends of elastic body 20 are secured to flexible tube 34, using annular member 36 at end 32 and annular member 37 at end 33. *See* Wallsten (Ex. 1) at col. 6, lines 35-66 and FIG. 6. On this ground alone, the Office has failed to establish a *prima facie* case of obviousness with respect to claim 36, and the rejection should be reversed. Applicants requested that the Office specifically explain how the asserted combination applies to this claim on pages 16 and 17 of their May 21, 2004 response, but the Office did not do so. Accordingly, the Office has not complied with 37 C.F.R. § 1.104(c)(2).

**C. The Office Fails to Carry Its Burden of Establishing a *Prima Facie* Case of Obviousness of Claim 67**

Claim 67 is directed to a device comprising a plurality of shape memory wires woven together to form a body useful for occluding an anatomical structure. The body has first and second ends. Both ends of at least one shape memory wire are located proximate one end of the body. The shape memory wires cross each other to form a plurality of cells and a plurality of angles. At least one of the angles is obtuse. At least one of the cells is defined by only four sides. The value of the at least one obtuse angle may be increased by axially compressing the body.

The reasoning provided above in section VII.A.1.a. about why the asserted combination of Wallsten and Sandock fails with respect to claims 1-16, 18 and 19 applies with equal force to the asserted obviousness of this claim. On those grounds, the obviousness rejection of claim 67 should be reversed.

**D. The Office Fails to Carry Its Burden of Establishing a *Prima Facie* Case of Obviousness of Claim 68**

Claim 68 is directed to a device comprising a body suitable for implantation into an anatomical structure. The body has an axis, a first end and a second end. The body comprises a shape memory wire having a first segment and a second segment. The segments are separated by a bend in the shape memory wire located proximate one end of the body. The first segment extends helically in a first direction around the axis toward the other end of the body. The second segment extends helically in a second direction around the axis toward the other end of the body. The first and second segments cross each other in a plurality of locations, and the first and second segments alternate being farther from the axis at each location. A non-limiting example of such a body is shown in FIG. 50B:

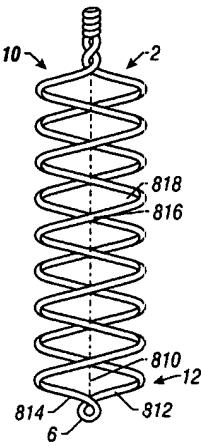


FIG. 50B

The Office has not provided much detail on how the asserted combination applies to this claim. In the final Office Action, the Office states:

As to claim 68, the Wallsten segments (wires) alternate being farther from the stent axis since they are woven as seen in figure 1a.

Final Office Action at p. 6. The problem with this assertion is that Wallsten disclose separate wires that each run the length of the stent, not a single wire that has one segment running the length of the stent helically in one direction and another segment running the length helically in another direction. *See* Wallsten (Ex. 1) at col. 4, line 63 – col. 5, line 6; claim 1. Thus, the asserted combination does not disclose or suggest all of the limitations of claim 68.

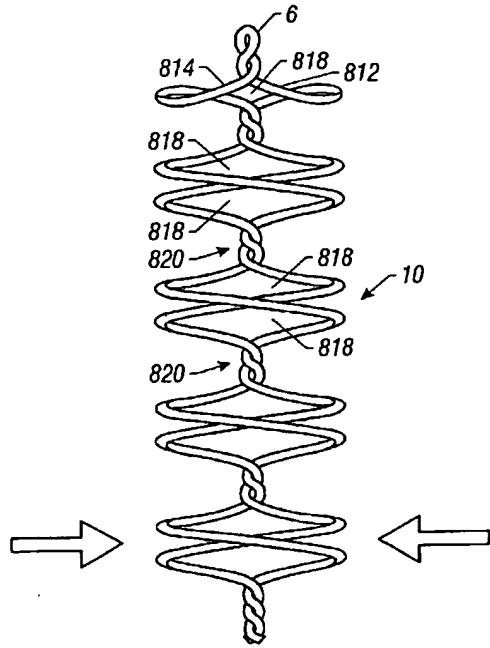
Wallsten discloses two wires that are connected together with a U-shaped member. Ex. 1 at col. 3, lines 33-41. Wallsten also discloses two wires that are connected together with a weld at their point of intersection, with the portions of the wires extending past the weld being folded inwardly. *Id.* at col. 3, lines 42-50. However, neither of these embodiments discloses or suggests a single wire that is bent with two segments extending helically as claimed.

Furthermore, Wallsten's statement of "the alternative in which no free ends at all are present is the alternative to make the tubular body as a whole of one coherent element" (Ex. 1 at col. 3, lines 30-33) does not describe or suggest how the one-wire stent is actually made. Therefore, it does not disclose the claimed bent wire and helically extending segments.

For these reasons, the Office has failed to carry its burden of establishing a *prima facie* case of obviousness with respect to claim 68. The rejection should therefore be reversed.

**E. The Office Fails to Carry Its Burden of Establishing a *Prima Facie* Case of Anticipation or Obviousness of Claim 69**

Claim 69 is directed to a device comprising a body suitable for implantation into an anatomical structure. The body has a first end and a second end, and comprises a shape memory wire having a first segment and a second segment. The segments are separated by a bend in the wire located proximate one end of the body. The first segment and second segment are arranged to form loops and twisted segments such that at least two contiguous substantially closed loops are separated from another loop by a twisted segment. A non-limiting example of such a body is shown in FIG. 50C:



**FIG. 50C**

The Office rejects claim 69 under section 102(e) as being anticipated by Hansen for the reasons set forth in the November 20, 2002 Office Action, page 6, lines 14-19. Final Office Action

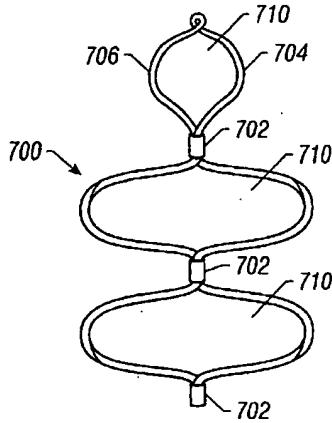
at p. 3. The Office then goes on to reject claim 69 under section 102(e) as being anticipated by or, alternatively under section 103(a) as being obvious over, Hansen. Final Office Action at pp. 3-4.

The shortcoming with the Office's reasoning is that the Office does not, nor can it, identify a **single wire** that forms the claimed loops and twisted segments, as claim 69 recites. All of the Office's arguments rely on shapes formed by more than one wire.

In the November 20, 2002 Office Action, the Office points to "2 loops" that are formed from different wires, not two segments of the same wire. Similarly, the heart shaped loops on which the Office relies in the final Office Action are formed from segments of different wires, not segments of the same wire. One need only follow the path of Hansen segments 10 and 11 of wire 13 (and of comparable segments of other wires) to see that this is true. *See* Hansen (Ex. 3). Accordingly, the Office has failed to carry its burden of establishing a *prima facie* case of anticipation or obviousness with respect to claim 69. The rejection should therefore be reversed.

#### **F. The Office Fails to Carry Its Burden of Establishing a *Prima Facie* Case of Anticipation or Obviousness of Claim 70**

Claim 70 recites a device comprising a body suitable for implantation into an anatomical structure. The body has two ends and comprises a shape memory wire having a first segment and a second segment. The segments are separated by a bend in the wire located proximate one end of the body. The segments are secured to each other in loop-defining locations. The segments also extend between the loop-defining locations in spaced relation to each other so as form at least two loops, at least one of the at least two loops having a compressed shape. A non-limiting example of such a body is shown in FIG. 57B:



**FIG. 57B**

The Office rejects claim 70 under section 102(e) as being anticipated by or, alternatively under section 103(a) as being obvious over, Hansen. Final Office Action at pp. 3-4. However, the Office does not, nor can it, identify a **single wire** in Hansen that forms a body. The bodies in Hansen are all formed from more than one wire, and there is no teaching or suggestion in Hansen that a single wire could be used to form a body suitable for implantation into an anatomical structure. *See* Hansen (Ex. 3) at col. 6, line 65 – col. 7, line 3. For this reason, the Office has failed to carry its burden of establishing a *prima facie* case of anticipation or obviousness with respect to claim 70, and the rejection should be reversed.

**G. The Office Fails to Carry Its Burden of Establishing a *Prima Facie* Case of Obviousness of Claims 71-86, 88 and 89**

Claims 71-86, 88 and 89 are patentable over the asserted combination of Wallsten and Sandock. The Office has failed to establish a *prima facie* case of obviousness with respect to these claims for the same reasons as those given above in section VII.A.1.a. This is all the more clear considering that claim 71 recites an intersection of two shape memory wires crossed in **non-interlocking** fashion because interlocking joints 13 are Sandock's focus. *See In re Fine*, 837 F.2d at 1074-75, 5 USPQ2d at 1599 (noting that teachings of one of cited references were "inconsistent with the claimed invention, to some extent").

Claims 73, 74 and 39 are patentable for additional, independent reasons.

**1. Claim 71**

Claim 71 is directed to a device comprising a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure. The body has a first end, a second end, and an intersection of two shape memory wires crossed in non-interlocking fashion. Both ends of at least one shape memory wire are located proximate one end of the body, and the two crossed wires form an obtuse angle that may be increased by axially compressing the body.

The reasoning provided above in section VII.A.1.a. about why the asserted combination of Wallsten and Sandock fails with respect to claims 1-16, 18 and 19 applies with equal force to the asserted obviousness of this claim and its dependent claims. On those grounds, the obviousness rejection of claims 71-86, 88 and 89 should be reversed. One of ordinary skill in the art would be further dissuaded from looking to Sandock because claim 71 recites two shape memory wires crossed in non-interlocking fashion, and Sandock's interlocking joints are critically important. *See In re Fine*, 837 F.2d at 1074-75, 5 USPQ2d at 1599 (noting that teachings of one of cited references were "inconsistent with the claimed invention, to some extent").

**2. Claim 73**

Claim 73 is separately patentable for an additional reason. Claim 73 recites that the shape memory wires comprise FePt, FePd or FeNiCoTi. The Office bases the rejection of this claim on the asserted combination of Wallsten and Sandock (Final Office Action at pp. 1-3), but neither reference teaches or suggests any of these materials. On this ground alone, the Office has failed to establish a *prima facie* case of obviousness with respect to claim 73, and the rejection should be reversed. Applicants requested that the Office specifically explain how the asserted combination

applies to this claim on pages 16 and 17 of their May 21, 2004 response, but the Office did not do so. Accordingly, the Office has not complied with 37 C.F.R. § 1.104(c)(2).

### **3. Claim 74**

Claim 74 is separately patentable for an additional reason. Claim 74 recites that the shape memory wires comprise FeNiC, FeMnSi or FeMnSiCrNi. The Office bases the rejection of this claim on the asserted combination of Wallsten and Sandock (Final Office Action at pp. 1-3), but neither reference teaches or suggests any of these materials. On this ground alone, the Office has failed to establish a *prima facie* case of obviousness with respect to claim 74, and the rejection should be reversed. Applicants requested that the Office specifically explain how the asserted combination applies to this claim on pages 16 and 17 of their May 21, 2004 response, but the Office did not do so. Accordingly, the Office has not complied with 37 C.F.R. § 1.104(c)(2).

### **4. Claim 89**

Claim 89 is separately patentable for an additional reason. Claim 89 depends from claim 88, which recites that the device of claim 71 further comprises a first tube configured to accept a guide wire; and a second tube configured to fit over the first tube. Claim 89 recites that the second tube is placed over the first tube, one end of the body is secured to the first tube and the other end of the body is secured to the second tube.

The Office bases the rejection of this claim on the asserted combination of Wallsten and Sandock (Final Office Action at pp. 1-3), but neither reference teaches or suggests a second tube placed over a first tube, one end of the claimed body being secured to the first tube, and the other end of the body being secured to the second tube. Wallsten discloses two tubes: thin-walled flexible tube 34 and outer flexible tube 35. However, both ends of elastic body 20 are secured to flexible tube 34, using annular member 36 at end 32 and annular member 37 at end 33. *See*

Wallsten (Ex. 1) at col. 6, lines 35-66 and FIG. 6. On this ground alone, the Office has failed to establish a *prima facie* case of obviousness with respect to claim 89, and the rejection should be reversed. Applicants requested that the Office specifically explain how the asserted combination applies to this claim on pages 16 and 17 of their May 21, 2004 response, but the Office did not do so. Accordingly, the Office has not complied with 37 C.F.R. § 1.104(c)(2).

#### **H. The Office Fails to Carry Its Burden of Establishing a *Prima Facie* Case of Obviousness of Claims 20-27, 29-33, 35 and 36**

Claims 90-105, 107 and 108 are patentable over the asserted combination of Wallsten and Sandock for the same reasons as claims 71-86, 88 and 89. Claims 92, 93 and 108 are patentable for additional, independent reasons.

##### **1. Claim 90**

Claim 90 is directed to a device comprising a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure. The body has a first end, a second end, a middle, and an intersection of two shape memory wires crossed in non-interlocking fashion. Both ends of at least one shape memory wire are located nearer one end of the body than the middle, and the two crossed wires form an obtuse angle that may be increased by axially compressing the body.

The reasoning provided above in section VII.A.1.a. about why the asserted combination of Wallsten and Sandock fails with respect to claims 1-16, 18 and 19 applies with equal force to the asserted obviousness of this claim and its dependent claims. On those grounds, the obviousness rejection of claims 90-105, 107 and 108 should be reversed. One of ordinary skill in the art would be further dissuaded from looking to Sandock because claim 90 recites two shape memory wires crossed in non-interlocking fashion, and Sandock's interlocking joints are critically important. *See*

*In re Fine*, 837 F.2d at 1074-75, 5 USPQ2d at 1599 (noting that teachings of one of cited references were “inconsistent with the claimed invention, to some extent”).

## **2. Claim 92**

Claim 92 is separately patentable for an additional reason. Claim 92 recites that the shape memory wires comprise FePt, FePd or FeNiCoTi. The Office bases the rejection of this claim on the asserted combination of Wallsten and Sandock (Final Office Action at pp. 1-3), but neither reference teaches or suggests any of these materials. On this ground alone, the Office has failed to establish a *prima facie* case of obviousness with respect to claim 92, and the rejection should be reversed. Applicants requested that the Office specifically explain how the asserted combination applies to this claim on pages 16 and 17 of their May 21, 2004 response, but the Office did not do so. Accordingly, the Office has not complied with 37 C.F.R. § 1.104(c)(2).

## **3. Claim 93**

Claim 93 is separately patentable for an additional reason. Claim 93 recites that the shape memory wires comprise FeNiC, FeMnSi or FeMnSiCrNi. The Office bases the rejection of this claim on the asserted combination of Wallsten and Sandock (Final Office Action at pp. 1-3), but neither reference teaches or suggests any of these materials. On this ground alone, the Office has failed to establish a *prima facie* case of obviousness with respect to claim 93, and the rejection should be reversed. Applicants requested that the Office specifically explain how the asserted combination applies to this claim on pages 16 and 17 of their May 21, 2004 response, but the Office did not do so. Accordingly, the Office has not complied with 37 C.F.R. § 1.104(c)(2).

## **4. Claim 108**

Claim 108 is separately patentable for an additional reason. Claim 108 depends from claim 107, which recites that the device of claim 90 further comprises a first tube configured to accept a

guide wire; and a second tube configured to fit over the first tube. Claim 108 recites that the second tube is placed over the first tube, one end of the body is secured to the first tube and the other end of the body is secured to the second tube.

The Office bases the rejection of this claim on the asserted combination of Wallsten and Sandock (Final Office Action at pp. 1-3), but neither reference teaches or suggests a second tube placed over a first tube, one end of the claimed body being secured to the first tube, and the other end of the body being secured to the second tube. Wallsten discloses two tubes: thin-walled flexible tube 34 and outer flexible tube 35. However, both ends of elastic body 20 are secured to flexible tube 34, using annular member 36 at end 32 and annular member 37 at end 33. *See* Wallsten (Ex. 1) at col. 6, lines 35-66 and FIG. 6. On this ground alone, the Office has failed to establish a *prima facie* case of obviousness with respect to claim 108, and the rejection should be reversed. Applicants requested that the Office specifically explain how the asserted combination applies to this claim on pages 16 and 17 of their May 21, 2004 response, but the Office did not do so. Accordingly, the Office has not complied with 37 C.F.R. § 1.104(c)(2).

## VIII. CONCLUSION

For all of these reasons, Applicants submit that the appealed claims meet the requirements of patentability. Therefore, Applicants request that the Board reverse the rejection of claims 1-16, 18-27, 29-33, 35, 36, 67-86, 88-105, 107 and 108.

Please date stamp and return the enclosed postcard to evidence receipt of this document.

Respectfully submitted,



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Date: May 10, 2005



## Claims Appendix

1. (previously presented) A device comprising:  
a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure, the body having first and second ends, the shape memory wires crossing each other to form a plurality of cells and a plurality of angles, at least one of the angles being obtuse, at least one of the cells being defined by only four sides, and both ends of at least one shape memory wire being located proximate one end of the body;  
wherein the value of the at least one obtuse angle may be increased by axially compressing the body.
2. (original) The device of claim 1, wherein the shape memory wires comprise nitinol.
3. (original) The device of claim 1, wherein the shape memory wires comprise FePt, FePd or FeNiCoTi.
4. (original) The device of claim 1, wherein the shape memory wires comprise FeNiC, FeMnSi or FeMnSiCrNi.
5. (original) The device of claim 1, wherein the shape memory wires each have a diameter ranging in size from about 0.006 inches to about 0.012 inches.
6. (original) The device of claim 1, wherein the plurality of shape memory wires includes at least 6 shape memory wires.
7. (original) The device of claim 1, wherein the body has a tubular shape with a substantially uniform diameter.
8. (original) The device of claim 1, wherein the body has a tapered shape with a diameter that decreases from one end of the body to the other end of the body.

9. (original) The device of claim 1, wherein the body has a generally hourglass shape.
10. (original) The device of claim 1, wherein the body is hand woven.
11. (original) The device of claim 1, wherein the body is machine woven.
12. (original) The device of claim 1, further comprising a graft material attached to the body.
13. (original) The device of claim 12, wherein the graft material comprises woven polyester.
14. (original) The device of claim 12, wherein the graft material comprises Dacron.
15. (original) The device of claim 12, wherein the graft material comprises polyurethane.
16. (original) The device of claim 12, wherein the graft material comprises PTFE.
17. (original) The device of claim 12, wherein the graft material partially covers the body.
18. (original) The device of claim 1, further comprising:  
a first tube configured to accept a guide wire; and  
a second tube configured to fit over the first tube.
19. (original) The device of claim 18, wherein the second tube is placed over the first tube, one end of the body is secured to the first tube and the other end of the body is secured to the second tube.
20. (previously presented) A device comprising:  
a body suitable for implantation into an anatomical structure, the body having a first end, a second end and being defined by at least n shape memory wires, wherein n is

greater than one, the  $n$  shape memory wires being arranged such that the body comprises a first portion, the first portion comprising a first woven portion and at least one strut, the shape memory wires of the first woven portion crossing each other to form a plurality of cells and a plurality of angles, at least one of the angles being obtuse, at least one of the cells being defined by only four sides, and both ends of at least one shape memory wire being located proximate one end of the body;

wherein the value of the at least one obtuse angle may be increased by axially compressing the body.

21. (original) The device of claim 20, wherein the shape memory wires comprise nitinol.
22. (original) The device of claim 20, wherein the shape memory wires comprise FePt, FePd or FeNiCoTi.
23. (original) The device of claim 20, wherein the shape memory wires comprise FeNiC, FeMnSi or FeMnSiCrNi.
24. (original) The device of claim 20, wherein the body further comprises a second portion adjacent the first portion, the second portion comprising a second woven portion, and the second portion having  $n + x$  shape memory wires, wherein  $x$  is at least one.
25. (original) The device of claim 20, wherein the first portion comprises a first woven portion separated from a second woven portion by multiple first struts.
26. (original) The device of claim 25, wherein the first portion has a generally domed shape.
27. (original) The device of claim 25, wherein the first woven portion has a generally domed shape and the multiple first struts are bent slightly so as to increase the self-anchoring capability of the body in an anatomical structure.

28. (original) The device of claim 25, wherein the first portion further comprises a third woven portion separated from the second woven portion by multiple second struts, and wherein the first and third woven portions have generally domed shapes.

29. (original) The device of claim 20, further comprising a graft material attached to the body.

30. (original) The device of claim 29, wherein the graft material comprises woven polyester.

31. (original) The device of claim 29, wherein the graft material comprises Dacron.

32. (original) The device of claim 29, wherein the graft material comprises polyurethane.

33. (original) The device of claim 29, wherein the graft material comprises PTFE.

34. (original) The device of claim 29, wherein the graft material partially covers the body.

35. (original) The device of claim 20, further comprising:  
a first tube configured to accept a guide wire; and  
a second tube configured to fit over the first tube.

36. (original) The device of claim 35, wherein the second tube is placed over the first tube, one end of the body is secured to the first tube and the other end of the body is secured to the second tube.

37. (withdrawn) A device comprising:  
a plurality of biodegradable filaments woven together to form a self-expanding body  
suitable for implantation into an anatomical structure, the self-expanding body

having first and second ends, the biodegradable filaments crossing each other to form a plurality of angles, at least one of the angles being obtuse; wherein the value of the at least one obtuse angle may be increased by axially compressing the self-expanding body.

38. (withdrawn) A method of creating a body suitable for implantation into an anatomical structure, the body having two ends, the method comprising:

bending the shape memory wires in a plurality of shape memory wires to create bent portions in the shape memory wires, the bent portions being arranged to define one end of the body, each shape memory wire having two ends; and

weaving the ends of the shape memory wires to create the body such that the shape memory wires cross each other to form a plurality of angles, at least one of the angles being obtuse;

wherein the value of the at least one obtuse angle may be increased by axially compressing the body.

39. (withdrawn) The method of claim 38, wherein the bent portions are bends.

40. (withdrawn) The method of claim 38, wherein the bent portions are loops.

41. (withdrawn) The method of claim 38, wherein the shape memory wires comprise nitinol.

42. (withdrawn) The method of claim 38, wherein the shape memory wires comprise FePt, FePd or FeNiCoTi.

43. (withdrawn) The method of claim 38, wherein the shape memory wires comprise FeNiC, FeMnSi or FeMnSiCrNi.

44. (withdrawn) The method of claim 38, wherein the shape memory wires each have a diameter ranging in size from about 0.006 inches to about 0.012 inches.

45. (withdrawn) The method of claim 38, wherein the plurality of shape memory wires includes at least 6 shape memory wires.

46. (withdrawn) The method of claim 38, wherein the body has a tubular shape with a substantially uniform diameter.

47. (withdrawn) The method of claim 38, wherein the body has a tapered shape with a diameter that decreases from one end of the body to the other end of the body.

48. (withdrawn) The method of claim 38, wherein the body has a generally hourglass shape.

49. (withdrawn) The method of claim 38, wherein the weaving is by hand.

50. (withdrawn) The method of claim 38, wherein the weaving is by machine.

51. (withdrawn) A method of creating a body suitable for implantation into an anatomical structure, the body having two ends, the method comprising:

providing a weaving system comprising:

a template having first template projections;

bending shape memory wires around the first template projections to create bent portions in the shape memory wires, the bent portions being arranged to define one end of the body, each shape memory wire having two ends; and

weaving the ends of the shape memory wires around the template to create the body such that the shape memory wires cross each other to form a plurality of angles, at least one of the angles being obtuse;

wherein the value of the at least one obtuse angle may be increased by axially compressing the body.

52. (withdrawn) The method of claim 51, wherein the first template projections comprise tabs.

53. (withdrawn) The method of claim 51, wherein the first template projections comprise pins.

54. (withdrawn) The method of claim 53, wherein the pins are attached to a ring engaged with the template.

55. (withdrawn) The method of claim 51, wherein the weaving system further comprises a first weaving plate configured to rotate in a first direction during the weaving.

56. (withdrawn) The method of claim 55, wherein the weaving system further comprises first bobbins arranged on the first weaving plate, one end of each shape memory wire being attached to each first bobbin prior to the weaving.

57. (withdrawn) The method of claim 55, wherein the weaving system further comprises a second weaving plate configured to rotate in a second direction during the weaving, the second weaving plate being spaced apart from the first weaving plate.

58. (withdrawn) The method of claim 57, wherein the weaving system further comprises second bobbins arranged on the second weaving plate, one end of each shape memory wire being attached to each second bobbin prior to the weaving.

59. (withdrawn) The method of claim 51, further comprising securing the shape memory wires to the template.

60. (withdrawn) The method of claim 51, further comprising forming closed structures with the ends of the shape memory wires, the closed structures being arranged to define the other end of the body.

61. (withdrawn) The method of claim 51, further comprising heating the body and the template.

62. (withdrawn) A device for delivering an axially and radially expandable woven body having two ends into an anatomical structure, comprising:

    a first tube configured to accept a guide wire; and

    a second tube configured to fit over the first tube;

    wherein when the tubes are used for delivering the axially and radially expandable woven body, one end of the axially and radially expandable woven body is secured to the outside of the first tube and the other end of the axially and radially expandable woven body is secured to the outside of the second tube.

63. (withdrawn) The device of claim 62, further comprising a guide wire configured to be placed within the first tube.

64. (withdrawn) The device of claim 62, further comprising a push-button release/lock mechanism configured to secure the first tube to the second tube.

65. (withdrawn) The device of claim 62, further comprising an end fitting having a side arm, the end fitting being configured to be secured to the first tube.

66. (withdrawn) A device for delivering an axially and radially expandable woven body having two ends into an anatomical structure, comprising:

    a first tube configured to accept a guide wire, the first tube having at least one pair of first tube holes positioned proximate one end of the first tube;

    a second tube configured to fit over the first tube, the second tube having at least one pair of second tube holes positioned proximate one end of the second tube;

    a first securing wire configured to be threaded through the at least one pair of first tube holes; and

a second securing wire configured to be threaded through the at least one pair of second tube holes;

wherein when the tubes are used for delivering the axially and radially expandable woven body, one end of the axially and radially expandable woven body is secured to the outside of the first tube with the first securing wire and the other end of the axially and radially expandable woven body is secured to the outside of the second tube with the second securing wire.

67. (previously presented) An occluding system comprising:  
a plurality of shape memory wires woven together to form a body useful for occluding an anatomical structure, the body having first and second ends, both ends of at least one shape memory wire being located proximate one end of the body, the shape memory wires crossing each other to form a plurality of cells and a plurality of angles, at least one of the angles being obtuse, and at least one of the cells being defined by only four sides;  
wherein the value of the at least one obtuse angle may be increased by axially compressing the body.

68. (previously presented) A device comprising:  
a body suitable for implantation into an anatomical structure, the body having an axis, a first end and a second end, wherein the body comprises a shape memory wire having a first segment and a second segment, the segments being separated by a bend in the shape memory wire located proximate one end of the body, the first segment extending helically in a first direction around the axis toward the other end of the body, the second segment extending helically in a second direction around the axis toward the other end of the body, the first and second segments crossing each other in a plurality of locations, and the first and second segments alternating being farther from the axis at each location.

69. (previously presented) A device comprising:  
a body suitable for implantation into an anatomical structure, the body having a first end and a second end, wherein the body comprises a shape memory wire having a first segment and a second segment, the segments being separated by a bend in the wire located proximate one end of the body, the first segment and second segments being arranged to form loops and twisted segments such that at least two contiguous substantially closed loops are separated from another loop by a twisted segment.

70. (previously presented) A device comprising:  
a body suitable for implantation into an anatomical structure, the body having two ends and comprising a shape memory wire having a first segment and a second segment, the segments being separated by a bend in the wire located proximate one end of the body, the segments being secured to each other in loop-defining locations, the segments also extending between the loop-defining locations in spaced relation to each other so as form at least two loops, at least one of the at least two loops having a compressed shape.

71. (previously presented) A device comprising:  
a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure, the body having a first end, a second end, and an intersection of two shape memory wires crossed in non-interlocking fashion;  
where both ends of at least one shape memory wire are located proximate one end of the body, and the two crossed wires form an obtuse angle that may be increased by axially compressing the body.

72. (previously presented) The device of claim 71, where the shape memory wires comprise nitinol.

73. (previously presented) The device of claim 71, where the shape memory wires comprise FePt, FePd or FeNiCoTi.

74. (previously presented) The device of claim 71, where the shape memory wires comprise FeNiC, FeMnSi or FeMnSiCrNi.

75. (previously presented) The device of claim 71, where the shape memory wires each have a diameter ranging in size from about 0.006 inches to about 0.012 inches.

76. (previously presented) The device of claim 71, where the plurality of shape memory wires includes at least 6 shape memory wires.

77. (previously presented) The device of claim 71, where the body has a tubular shape with a substantially uniform diameter.

78. (previously presented) The device of claim 71, where the body has a tapered shape with a diameter that decreases from one end of the body to the other end of the body.

79. (previously presented) The device of claim 71, where the body has a generally hourglass shape.

80. (previously presented) The device of claim 71, where the body is hand woven.

81. (previously presented) The device of claim 71, where the body is machine woven.

82. (previously presented) The device of claim 71, further comprising a graft material attached to the body.

83. (previously presented) The device of claim 82, where the graft material comprises woven polyester.

84. (previously presented) The device of claim 82, where the graft material comprises Dacron.

85. (previously presented) The device of claim 82, where the graft material comprises polyurethane.

86. (previously presented) The device of claim 82, where the graft material comprises PTFE.

87. (previously presented) The device of claim 82, where the graft material partially covers the body.

88. (previously presented) The device of claim 71, further comprising:  
a first tube configured to accept a guide wire; and  
a second tube configured to fit over the first tube.

89. (previously presented) The device of claim 88, where the second tube is placed over the first tube, one end of the body is secured to the first tube and the other end of the body is secured to the second tube.

90. (previously presented) A device comprising:  
a plurality of shape memory wires woven together to form a body suitable for implantation into an anatomical structure, the body having a first end, a second end, a middle, and an intersection of two shape memory wires crossed in non-interlocking fashion;  
where both ends of at least one shape memory wire are located nearer one end of the body than the middle, and the two crossed wires form an obtuse angle that may be increased by axially compressing the body.

91. (previously presented) The device of claim 90, where the shape memory wires comprise nitinol.

92. (previously presented) The device of claim 90, where the shape memory wires comprise FePt, FePd or FeNiCoTi.

93. (previously presented) The device of claim 90, where the shape memory wires comprise FeNiC, FeMnSi or FeMnSiCrNi.

94. (previously presented) The device of claim 90, where the shape memory wires each have a diameter ranging in size from about 0.006 inches to about 0.012 inches.

95. (previously presented) The device of claim 90, where the plurality of shape memory wires includes at least 6 shape memory wires.

96. (previously presented) The device of claim 90, where the body has a tubular shape with a substantially uniform diameter.

97. (previously presented) The device of claim 90, where the body has a tapered shape with a diameter that decreases from one end of the body to the other end of the body.

98. (previously presented) The device of claim 90, where the body has a generally hourglass shape.

99. (previously presented) The device of claim 90, where the body is hand woven.

100. (previously presented) The device of claim 90, where the body is machine woven.

101. (previously presented) The device of claim 90, further comprising a graft material attached to the body.

102. (previously presented) The device of claim 101, where the graft material comprises woven polyester.

103. (previously presented) The device of claim 101, where the graft material comprises Dacron.

104. (previously presented) The device of claim 101, where the graft material comprises polyurethane.

105. (previously presented) The device of claim 101, where the graft material comprises PTFE.

106. (previously presented) The device of claim 101, where the graft material partially covers the body.

107. (previously presented) The device of claim 90, further comprising:  
a first tube configured to accept a guide wire; and  
a second tube configured to fit over the first tube.

108. (previously presented) The device of claim 107, where the second tube is placed over the first tube, one end of the body is secured to the first tube and the other end of the body is secured to the second tube.

## **Evidence Appendix**

Copies of U.S. Patent Nos. 4,655,771 ("Wallsten"), 5,800,519 ("Sandock") and 5,968,088 ("Hansen") are attached as Exs. 1, 2 and 3, respectively, of this Evidence Appendix.